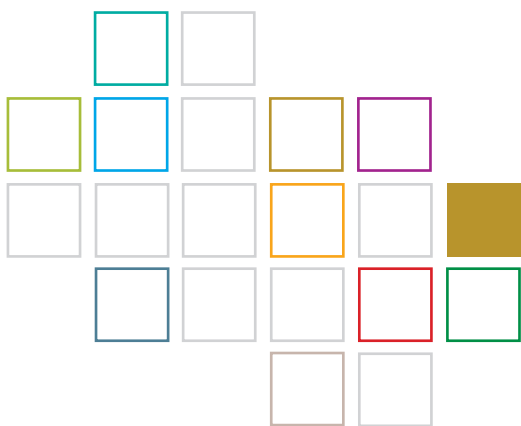


Drug-Device Combination Products for Parenteral Use



25 - 26 June 2024
Basel, Switzerland
Course no. 6998



Hot Topics

Target group

Scientists and professionals involved in the research, development and manufacture of drug-device combination products for parenteral use (small molecules, biologics and vaccines), including formulation, device and analytical experts R&D managers, Business Development & Licensing managers, project/ programme managers, academic researchers, device development design engineers.



This seminar is organised by the focus group Drug Delivery and Biotechnology

Objectives

Devices and drugs (scope):

- Autoinjectors
- Prefilled syringes
- Injection systems with mixing/reconstitution functionality
- Wearable injection devices
- Digitally connected systems
- Systems for special sites of administration (intrathecal, ophthalmic)
- Drugs: small molecules, monoclonal antibodies and other proteins, vaccines
- CSTDs (currently a really hot topic!)

Moderators



Karoline Bechtold-Peters
Novartis, Basel, Switzerland

Dr. Karoline Bechtold-Peters is pharmacist and received her doctorate from the Ludwigs-Maximilians-University of Munich in Pharmaceutical Technology in 1994 for a thesis in the field of enteric-coated pancreatin pellets. In 1994, Karoline started at Boehringer Ingelheim in Ingelheim as Head of Laboratory in Solid Dosage Forms, focusing on powder inhalation therapeutics. In this context, Karoline was instrumental in the development of the blockbuster Spiriva. In 2000, she moved to the Business Unit Biopharmaceuticals of Boehringer Ingelheim and thus to Biberach to build-up Formulation Development of Therapeutic Proteins. In 2003 she was appointed 2003 Head of Global Clinical Supplies, Aseptic Process Development and Process Transfer. After several years in this position, Karoline moved to Basel, Switzerland, in 2011, to join Hoffmann La-Roche and was assigned Head of Drug Product Clinical Supply Center Basel within Global Biologics Europe and was responsible for the production of biopharmaceutical clinical supplies both for Roche and Genentech. It became her core task to ramp up the brand new clinical lines for sterile vials and syringes covering initial inspections and initial batch production from 2011 to 2013. The expansion of the production to Antibody-Drug-Conjugates followed. In 2016, Karoline joined Novartis Pharma AG in Basel to focus on more strategic and future-looking issues of Biopharmaceuticals as Senior Strategy and Technology Leader Pharmaceuticals within Biologics Technical Development & Manufacturing (BTDM) and the team "BioFuture". Since the reorganization of the Biologics business, Karoline has been part of the Scientific Offices Drug Product Development within Global Biologics & Cell and Gene Therapy as Director Science & Technology, representing the focus on Innovation and External Engagement.



Karsten Cremer
Pharma Patents, Basel, Switzerland

Karsten Cremer is a pharmaceutical scientist and IP expert with substantial experience in drug delivery and drug product development. In his current role as founder and managing partner of Pharma Patents International, an IP firm specialised in the pharmaceutical sector, one of his focus areas is innovation in drug delivery devices. In previous appointments, he was CEO of Capsulation Nano Science AG, Director of Oral Drug Delivery at LTS Lohmann Therapy Systems, and Lecturer of Pharmaceutics at the University of Marburg. Karsten is also a founder and member of the APV Drug Delivery Focus Group which sponsors the present programme. He holds a PhD in Pharmaceutical Technology and Biopharmaceutics from the University of Heidelberg, Germany.



Alphons Fakler
Novartis, Basel, Switzerland

Alphons Fakler graduated as a pharmacist from Ludwig-Maximilian-University Munich and holds a post-graduate degree in Applied Statistics from Swiss Federal Institute of Technology Zurich. For more than 20 years he worked in various roles around analytical devices, pharmaceutical packaging, medical devices (including Software as Medical Device) and combination products. His areas of responsibility spanned a wide range from project management, risk management, organizational design, external partner management and building and leading high performing teams to change management, operational excellence, driving corporate culture and corporate communication. In his current position he is leading the Human Factors Engineering team within Novartis' Global Packaging and Device Development. For many years Alphons is involved in external engagement activities like speaking and chairing at conferences and participating in technical committees and consortia.

Drug-Device Combination Products for Parenteral Use

Programme

Tuesday, 25 June 2024

10:00 - 18:00 h

Welcome

Alphones Fakler, Karoline Bechtold-Peters, Novartis, and Karsten Cremer, Pharma Patents, Basel, Switzerland

Implementation sciences: closing the gap between what we know and what we do.

Mahrukh Zahid, Novartis, Basel, Switzerland

Session 1 - Setting the stage

Market overview / trends /outlook

Manfred Maeder, Novartis, Basel, Switzerland

Parenteral product development strategies - an overview / big picture – early versus late LCM

Mario Hirth, Abbvie, Ludwigshafen, Germany

Lessons learnt to certify a QMS and product against the new EU MDR

Mike Wallenstein, Novartis, Basel, Switzerland

Session 2 - Tech focus

New regulatory environment and new guidance in Europe including the role of Notified Bodies

Vikas Jaitely, Merck Group, Eysins, Switzerland

Autoinjectors and patch injectors - new trends in AIs and OBIs

Paulo Mangiagalli, Sanofi, Nanterre, France

Formulation development for drug-device com-bos incl. high dose, high viscosity, silicone oil interaction

Wolfgang Friess, LMU University Munich, Germany

Analytical challenges of drug-device combos and special methods

Andrea Hawe, Coriolis, Martinsried, Germany

Designing injection devices for environmental sustainability

Nanja Kløverpris, Novo Nordisk, Copenhagen, Denmark

Roundtable with device companies

Representatives from packaging and device companies

Closure Day 1

Networking dinner

Wednesday, 26 June 2024

09:00 - 16:00 h

Welcome

Alphones Fakler, Karoline Bechtold-Peters, Novartis, and Karsten Cremer, Pharma Patents, Basel, Switzerland

Technical challenges session

- Needle clogging (sources and mitigation)
Katharina Golly, Novartis, Basel, Switzerland
- Intravitreal injections and related challenges
Alphones Fakler, Novartis, Basel, Switzerland
- Particles in drug-device combination products
Klaus Wuchner, Janssen R&D, Schaffhausen, Switzerland
- Needle geometries (thin walled, consistency of diameter)
speaker tbd
- From standard needle safety to integrated needle safety
Oliver Rausch, Boehringer Ingelheim, Ingelheim, Germany
- Closed system drug transfer devices (CSTD)
Jonas Fast, Roche, Basel, Switzerland

Session 3 - Patient focus

Presentation on SubQ consortium activities

Sylvain Huille, Sanofi, Paris, France

Modelling & simulation as applied for combination drug product development and characterization

Speaker tbc

Session 4 – Business focus

Life cycle management, bridging strategies, reimbursement aspects

Beate Bittner, Roche, Basel, Switzerland

Patent landscape, IP trends and challenges for drug-device combos

Karsten Cremer, Pharma Patents, Basel, Switzerland

Business aspects of collaborative product development (pharma & device technology providers) - with roundtable with discussion of challenges experienced by both sides?

Roundtable with panellist

Final discussion and course closing

Programme subject to changes.

Table top exhibitors



Location	Registration fee	Registration	Hotel reservation
Novartis Campus Fabrikstrasse 2 4056 Basel Switzerland	Until 15 April 2024 Industry 1590 EUR Authority/University 795 EUR Students* 250 EUR	APV-Geschäftsstelle Kurfürstenstraße 59 55118 Mainz/Germany Phone: 0049 6131 97 69 0 E-mail: apv@apv-mainz.de Web: www.apv-mainz.de	We kindly ask you to book your hotel yourself . We recommend booking platforms such as booking.com or hrs.com
	From 16 April 2024 Industry 1690 EUR Authority/University 845 EUR Students* 290 EUR		
Date	(free of VAT according to § 4,22 UStG) Coffee breaks, luncheon, dinner and electronic proceedings included. * Limited places for full time students available; written evidence must be submitted.		
Course no.: 6998 from 25 June 2024 to 26 June 2024	10:00 h 16:00 h	You will receive a confirmation of your registration with the invoice.	

Drug-Device Combination Products for Parenteral Use, 25 - 26 June 2024, Basel, CH, Course no. 6998

Registration

As soon as you have found a seminar of your interest, it is very easy to register for it by e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

Registration confirmation

After your registration was successfully processed, you will receive a confirmation.

Before the event

A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event

You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

Follow-up

After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

Declaration of consent in respect of data protection

By registering for this seminar, I agree that the APV uses my data for the purpose of processing the order and provides me with all relevant information.

I also agree that APV may contact me for the purpose of exchanging similar information by email or post.

Your data will not be shared with third parties. You have a right of withdrawal at any time without giving reasons.

All other information can be found in our privacy policy (www.apv-mainz.de/en/imprint/data-protection-statement/).

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Gemeinnütziger wissenschaftlicher Verein
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APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany

Phone: 0049 6131 97 69 0
E-mail apv@apv-mainz.de

www.apv-mainz.de/en